WHAT IS CLAIMED IS:

1. An isolated, synthetic, or recombinant polynucleotide comprising a smooth muscle myosin heavy chain (SM-MHC) promoter/enhancer sequence, wherein said promoter/enhancer is capable of conferring smooth muscle specific expression *in vivo*.

2. The polynucleotide of claim 1, wherein the promoter sequence consists essentially of a sequence selected from the group consisting of:

(i) the region of nucleotides 5663 to 5889 of SEQ ID NO:16;

(ii) SEQ ID NO:16 except that CArG2 has been mutated;

(iii) SEQ ID NO:16 except that the intronic CArG has been mutated;

(iv) the regions of nucleotides 1 to 6,700 and nucleotides 9,500 to 15,800 of SEQ ID NO:16;

(v) the regions of nucleotides 1 to 9,500 and nucleotides 11,700 to 13,700 of SEQ ID NO:16;

(vi) SEQ ID NO:16; and

(vii) SEQ ID NO:17.

3. A polynucleotide which is capable of conferring smooth muscle cell (SMC) specific expression, wherein the polynucleotide hybridizes under stringent conditions to the SM-MHC promoter/enhancer of claim 2.

4. The polynucleotide of claim 1, further comprising a heterologous polynucleotide operably linked to the SM-MHC promoter sequence.

5. The polynucleotide of claim 4, wherein the heterologous polynucleotide encodes a polypeptide.

6. The polynucleotide of claim 5, wherein the polypeptide is selected from the group consisting of a toxin, a prodrug-converting enzyme, a tumor suppressor, a sensitizing agent, an apoptotic factor, an angiogenesis inhibitor, a cytokine, and an immunogenic antigen.

7. The polynucleotide of claim 4, wherein the heterologous polynucleotide is selected from the group consisting of an antisense polynucleotide and a catalytic polynucleotide.

8. An expression vector comprising a smooth muscle myosin heavy chain (SM-MHC) promoter/enhancer sequence, wherein the promoter sequence consists essentially of a sequence selected from the group consisting of:

(i) the region of nucleotides 5663 to 5889 of SEQ ID NO:16;

(ii) SEQ ID NO:16 except that CArG2 has been mutated;

(iii) SEQ ID NO:16 except that the intronic CArG has been mutated;

(iv) the regions of nucleotides 1 to 6,700 and nucleotides 9,500 to 15,800 of SEQ ID NO:16;

(v) the regions of nucleotides 1 to 9,500 and nucleotides 11,700 to 13,700 of SEQ ID NO:16;

(vi) SEQ ID NO:16; and

(vii) SEQ ID NO:17.

9. The expression vector of claim 8 that is a retroviral vector, an adeno-associated viral vector, or an adenoviral vector.

10. The expression vector of claim 8, wherein the promoter sequence is operably linked to a heterologous polynucleotide.

11. The expression vector of claim 10, wherein the heterologous polynucleotide encodes a polypeptide.

12. The expression vector of claim 11, wherein the polypeptide is selected from the group consisting of a toxin, a prodrug-converting enzyme, a tumor suppressor, a sensitizing agent, an apoptotic factor, an angiogenesis inhibitor, a cytokine, and an immunogenic antigen.

13. The expression vector of claim 10, wherein the polynucleotide is selected from the group consisting of an antisense polynucleotide and a catalytic polynucleotide.

14. The expression vector of claim 8, wherein the promoter consists essentially of the sequence of SEQ ID NO:16 except that CArG2 or the intronic CArG has been mutated.

15. The expression vector of claim 14, wherein CArG2 has been changed from TTCCTTTTATGG (SEQ ID NO:1) to GGATCCTATGG (SEQ ID NO:2).

16. The expression vector of claim 14, wherein the intronic CArG has been changed from CCTTGTATGG (SEQ ID NO:5) to AGGCCTATGG (SEQ ID NO:6).

17. A genetically engineered host cell comprising the vector of claim 8.

18. A transgenic, non-human animal containing the polynucleotide of claim 2.

19. A composition comprising the polynucleotide of claim 1 in a pharmaceutically acceptable carrier.

20. A method of expression a polynucleotide in a smooth muscle cell *in vivo* comprising, introducing into said smooth muscle cell said polynucleotide operably linked to an SM-MHC promoter/enhancer sequence, wherein said promoter/enhancer is capable of conferring smooth muscle specific expression *in vivo*.

21. The method of claim 20, wherein the SM-MHC promoter/enhancer consists essentially of a sequence selected from the group consisting of:

(i) the region of nucleotides 5663 to 5889 of SEQ ID NO:16;

(ii) SEQ ID NO:16 except that CArG2 has been mutated;

(iii) SEQ ID NO:16 except that the intronic CArG has been mutated;

(iv) the regions of nucleotides 1 to 6,700 and nucleotides 9,500 to 15,800 of SEQ ID NO:16;

(v) the regions of nucleotides 1 to 9,500 and nucleotides 11,700 to 13,700 of SEQ ID NO:16;

(vi) SEQ ID NO:16; and

(vii) SEQ ID NO:17.

22. The method of claim 20, wherein said polynucleotide is a reporter gene or encodes a therapeutic protein.

23. The method of claim 20, wherein said SM-MHC promoter/enhancer consists essentially of the regions of nucleotides 1 to 9,500 and nucleotides 11,700 to 13,700 of SEQ ID NO:16.

24. The method of claim 23, wherein said smooth muscle cell is of coronary artery, aorta, airway smooth muscle, or pulmonary vascular smooth muscle.

25. The method of claim 20, wherein said SM-MHC promoter/enhancer consists essentially of the regions of nucleotides 1 to 6,700 and nucleotides 9,500 to 15,800 of SEQ ID NO:16.

26. The method of claim 25, wherein said smooth muscle cell is of aorta, pulmonary airway, or pulmonary vascular smooth muscle.

27. The method of claim 20, wherein the SM-MHC promoter/enhancer consists essentially of the sequence of SEQ ID NO:16 except that CArG2 has been mutated.

28. The method of claim 27, wherein the smooth muscle cell is of bladder smooth muscle, gastrointestinal tract smooth muscle, or urinary tract smooth muscle.

29. The method of claim 20, wherein the SM-MHC promoter/enhancer consists essentially of the sequence of SEQ ID NO:16 except that the intronic CArG has been mutated.

30. The method of claim 29, wherein the smooth muscle cell is of gastrointestinal tract smooth muscle, urinary tract smooth muscle, airway smooth muscle, vein smooth muscle, or small branching artery smooth muscle.

31. The method of claim 20, wherein the SM-MHC promoter/enhancer consists essentially of nucleotides 5663 to 5889 of SEQ ID NO:16.

32. The method of claim 31, wherein the SM-MHC promoter/enhancer further comprises a minimal thymidine kinase (TK) promoter.

33. The method of claim 32, wherein the smooth muscle cell is of aorta artery smooth muscle, carotid artery smooth muscle, pulmonary artery smooth muscle, vena cava vein smooth muscle, or vascular smooth muscle.

34. A method for screening a compound that modulates the activity of an SM-MHC promoter/enhancer comprising:

(i) contacting a test compound with a cell or an animal model system containing the SM-MHC promoter/enhancer operably linked to a reporter gene;

(ii) detecting expression of the reporter gene; and

(iii) comparing the expression detected in (ii) to the amount of expression obtained in the absence of the test compound;

such that if the level obtained in (ii) is higher or lower than that obtained in the absence of the test compound, a compound that modulates the activity of the SM-MHC promoter/enhancer has been identified.